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United States Food Law Update: Food Safely Planning, Attribute Labeling, and the Irradiation Debate

Bryan Endres
University of Illinois

UNITED STATES FOOD LAW UPDATE: FOOD SAFETY PLANNING, ATTRIBUTE LABELING, AND THE IRRADIATION DEBATE

*A. Bryan Endres**

I. INTRODUCTION

This article summarizes significant changes and developments in food law throughout the second half of 2007. The previous edition of the *Food Law Update*[1] noted the recent increase in imported food[2] and the resulting stress placed on food safety agencies and customs officials. Detailed inspections of every food shipment entering the United States would quickly exhaust limited agency resources and cripple efficient international trade of food products.[3] On the other hand, after several well-publicized food scares and the ongoing threat of international contamination, the public increasingly demands high levels of physical surveillance. As a part of this ongoing discussion, this update examines the Food and Drug Administration's (FDA) new Food Protection Plan issued in November 2007.

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1. A. Bryan Endres, *United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imported Food*, 3 J. FOOD L. & POL'Y 253 (2007).

2. In 2006, the United States imported more than $65 billion of agricultural products, an increase of almost $20 billion since 2003. Econ. Res. Serv. (ERS), U.S. Dep't of Agric. (USDA), *Foreign Agricultural Trade of the United States*, http://www.ers.usda.gov/Data/FATUS/index.htm#value (follow "Total value of U.S. agricultural trade and trade balance, monthly" hyperlink; last visited July 15, 2008).

3. The White House, *Fact Sheet: Import Safety Action Plan: Increasing Protection of American Consumers* (Nov. 6, 2007), *available at* http://www.whitehouse.gov/news/releases/2007/11/20071106-7.html.

With respect to domestic food sourcing, several issues warrant analysis in this update, many centering on various forms of livestock production. The United States Department of Agriculture (USDA) finally promulgated regulations in October 2007 for process-verified "grass fed" meat marketing claims. Originally proposed in 2002 and revised in 2006, the agency's 2007 final standard illustrates the difficulty of reconciling consumer expectations with industry concerns regarding production costs and regulatory mandates.

Consumer expectations were also the driving force behind two important developments in the organic industry during the second half of 2007. First, the Cornucopia Institute challenged the organic certification of three large-scale dairy operations alleging willful noncompliance with National Organic Program (NOP) standards. Second, the National Organic Standards Board (NOSB) finalized amendments to the National List of Allowed and Prohibited Substances–a key list for the continued expansion of the organic processed food market.

Finally, this article will address a controversial food labeling proposal that is at the intersection of scientific advancement, food safety, and consumer skepticism–irradiation in food production. Although this update generally does not report on "pending" issues, the intensity of public scrutiny for this particular labeling change warrants discussion at this time.

Out of necessity, this article does not include every development in food law from the second half of 2007; rather, it is limited to significant changes in national law. The motivation for this series of updates is to provide a starting point for scholars, practitioners, food scientists, and policymakers determined to understand the shaping of food law in modern society. Tracing the development of food law though these updates also builds an important historical context for the overall development of this exciting and evolving discipline.

II. FDA FOOD PROTECTION PLAN

A. Interagency Action Plan for Import Safety

The last *Update* briefly described the Bush Administration's efforts to improve domestic and imported food safety in the wake of highly-publicized crises such as melamine contamination of pet food linked to Chinese raw materials, and fatal *E. coli* outbreaks traced to

raw spinach. In September 2007, an interagency working group[4] issued a report to the President outlining a strategic plan for improving the safety of imported products, including food.[5] The group published its roadmap for reform and action plan (Action Plan) in November 2007.[6]

The Action Plan's foundation is a three-pronged strategy of prevention, intervention, and response, with emphasis shifted from intervention to prevention throughout the life cycle of a product.[7] Six cross-cutting "building blocks" inform the three-pronged strategy: (1) advancing a common governmental vision for import safety; (2) increasing private-sector accountability for the safety of imported products, including increased enforcement and deterrence; (3) focusing on risks at the critical life cycle stages of an imported product; (4) building interoperable systems for the exchange of information between agencies; (5) fostering a culture of collaboration within government and between government and stakeholders; and (6) promoting technological innovation and new science.[8] In addition to recommendations and proposed action steps for each of the three prongs (prevention, intervention, and response),[9] the Action Plan promises that within 200 days of its issuance, agencies will take certain actions to immediately protect American consumers.[10]

Initial Action Plan activities include enhancement of the National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program.[11] NOAA will inspect and certify additional Chinese seafood processing plants and will place additional inspectors in locations where large amounts of imported seafood originate.[12] The United States also continued to negotiate agreements with China to "enhance regulatory cooperation" for food and ani-

4. President Bush established the Interagency Working Group on Import Safety through Executive Order 13439, 72 Fed. Reg. 40051 (July 20, 2007).

5. INTERAGENCY WORKING GROUP ON IMPORT SAFETY, PROTECTING AMERICAN CONSUMERS EVERY STEP OF THE WAY: A STRATEGIC FRAMEWORK FOR CONTINUAL IMPROVEMENT IN IMPORT SAFETY (Sept. 10, 2007), *available at* http://www.importsafety.gov/report/report.pdf.

6. INTERAGENCY WORKING GROUP ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT (Nov. 2007), *available at* http://www.importsafety.gov/report/actionplan.pdf [hereinafter ACTION PLAN].

7. *Id.* at 5.

8. *Id.* at 6-7.

9. *Id.* at 11.

10. *Id.* at 9.

11. ACTION PLAN, *supra* note 6, at 9.

12. *Id.*

mal feed.[13] The United States Department of Agriculture (USDA) and the Food and Drug Administration (FDA) conducted a seven-week training program for Chinese meat, poultry, and egg inspectors regarding United Sates food safety standards.[14] President Bush also pledged in August 2007 to increase trilateral cooperation to combat unsafe food imports through the Security and Property Partnership (SPP) between the United States, Mexico, and Canada.[15] And to eliminate port-shopping of food initially refused entry, the Action Plan promises to implement by mid-July 2008 a rule requiring the marking of rejected food imports as "refused entry."[16]

B. FDA Food Protection Plan

Perhaps the most prominent action taken as part of the Import Safety Action Plan with regard to food safety is the FDA Food Protection Plan (FPP).[17] The FPP recognizes that while the number of high-risk consumers (e.g., the elderly, very young, and immune-compromised) continues to increase,[18] food imports (on which the FDA admits it has limited information)[19] also have risen dramatically.[20] America's growing appetite for ready-to-eat foods and a year-round supply of fresh fruits and vegetables, both of which increas-

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13. *Id.*; *see also* Steven Suppan, Inst. for Ag. & Trade Pol'y, *U.S. China Agreement on Food Safety: Terms and Capacity* (May 2008), *available at* http://www.iatp.org/tradeobservatory/library.cfm?refID=102837 (describing in more detail the December 2007 Memorandum of Agreement on food and feed safety); China CSR, *China Inks Food Safety Agreement with U.S.* (June 23, 2008), http://www.chinacsr.com/2008/06/23/2454-china-inks-food-safety-agreement-with-united-states (last visited July 15, 2008) (discussing the Joint Progress Statement issued by China and the U.S in June 2008 outlining the steps taken to implement the December 2007 Memorandum of Agreement on food and feed safety, including establishment of communication points of contact in case of a food or feed safety event, threshold levels that trigger notifications, and enhanced information exchange to foster understanding of each country's regulatory system).

14. ACTION PLAN, *supra* note 6, at 9.

15. *Id.*

16. *Id.*; *see also* Regulatory Agenda, 73 Fed. Reg. 24682, 24683 (May 5, 2008) (stating that a notice of proposed rulemaking regarding port shopping and imported food will issue in July 2008).

17. FOOD & DRUG ADMIN. (FDA), FOOD PROTECTION PLAN: AN INTEGRATED STRATEGY FOR PROTECTING THE NATION'S FOOD SUPPLY (Nov. 2007), *available at* http://www.fda.gov/oc/initiatives/advance/food/plan.html [hereinafter FOOD PROTECTION PLAN].

18. *Id.* at 7.

19. *Id.* at 6-7.

20. *Id.* at 8.

ingly are imported to meet consumer demand, further compound vulnerability to foodborne illness.[21] Moreover, the FDA and the scientific community must continually develop new testing protocols to confront the emergence of new foodborne pathogens.[22]

The FPP reiterates the interagency Action Plan's three-pronged prevention, intervention, and response approach to food emergencies related to both intentional ("food defense") and unintentional ("food safety") contamination.[23] For each prong, the FDA examines both the ways in which it can strengthen its existing actions, as well as the need for additional legislative authority, if any, to meet the Action Plan's goals.[24]

1. Prevention

The FPP places greater emphasis on "building safety into products right from the start," working more closely with industry, state, local, and foreign governments to "further develop the tools and science needed to identify vulnerabilities and determine the most effective [mitigation] approaches."[25] The FDA emphasizes increased corporate responsibility, and indicates that it will seek additional regulatory authority to require food handlers to take specific steps, based on risk assessments, aimed solely at preventing intentional contamination of bulk food prior to packaging (e.g., locks on tanker trucks).[26] The FDA further proposes that firms that comply with these controls would have an affirmative defense in civil litigation.[27] The agency also seeks specific authority to implement food safety procedures for high-risk foods (e.g., HACCP),[28] to require facilities

21. *Id.* at 6-7.

22. FOOD PROTECTION PLAN, *supra* note 17, at 8.

23. *Id.* at 3, 11-13.

24. In May 2008, the FDA issued a notice requesting comments from the public and stakeholders on its Food Protection Plan. Food Protection Plan, Outreach Activities, Opportunity for Public Comment, 73 Fed. Reg. 17987 (Apr. 2, 2008). In addition, the FDA announced the availability of grant funding for meetings of state food protection task forces to align with the goals and mandates stemming from the Food Protection Plan. Food Protection Task Force Conference, 73 Fed. Reg. 32715 (June 10, 2008).

25. FOOD PROTECTION PLAN, *supra* note 17, at 11.

26. *Id.* at 15. The regulations would not apply to raw produce or food on farms. *Id.*

27. *Id.*

28. *Id.* The FDA issued a final rule in May 2008, as part of a Food Protection Plan action item, on prevention of *Salmonella enteritidis* in shell eggs. *See* Regulatory Agenda, 73 Fed. Reg. 24684 (May 5, 2008).

to register every two years,[29] and to create new food categories within the registration system to better tailor registration to particular hazard risks.[30] The FDA may also develop written food protection guidelines for produce and other food products, as well as other corporate responsibility measures.[31]

On the international scale, the FDA pledged to improve its presence overseas, starting with increased dialogue with foreign governments to develop approaches for improving food safety.[32] It will focus foreign inspections on high-risk firms and products, and will provide increased technical assistance to foreign countries so as to improve their regulatory systems for food safety.[33]

2. Intervention

There are three key intervention proposals in the Food Protection Plan: focusing inspection and sampling based on risk, enhancing risk-based surveillance, and improving detection of food system "signals" that indicate contamination.[34] The FDA indicates that it will seek additional authority to certify third parties as food inspectors and to require food manufacturers that fail to meet current good manufacturing practices (GMPs) to reapply, and pay for, reinspections.[35] The agency hopes to shift some of the inspection burden to regulatory authorities in exporting countries by requiring electronic import certificates for high-risk foods.[36] The FDA will seek authority from Congress to prohibit food imports when its access to the foreign facility for inspection has been denied, limited, or delayed.[37] In order to detect contamination earlier, the FDA will improve reporting systems and deploy improved screening tools.[38]

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29. FOOD PROTECTION PLAN, *supra* note 17, at 15; Regulation of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58893 (Oct. 10, 2003) (issuing interim final ruling on the registration of food facilities under the 2002 Public Health Security and Bioterrorism Preparedness and Response Act of 2002). Currently, facilities only are required to register once, but must update information within sixty days if registration information changes. 21 C.F.R. § 1.234 (2007).

30. FDA FOOD PROTECTION PLAN, *supra* note 17, at 15.

31. *Id.* at 14.

32. *Id.* at 16.

33. *Id.*

34. *Id.* at 17.

35. FOOD PROTECTION PLAN, *supra* note 17, at 18.

36. *Id.* at 19-20.

37. *Id.* at 20.

38. *Id.* at 21.

3. Response

When prevention and intervention fail, the FPP proposes to improve the FDA's immediate response to food safety problems and communication of such problems to the public and stakeholders.[39] The FDA concludes that this will require additional legislative authority to issue mandatory food recalls and to gain increased access to safety and security records during the emergency by eliminating the need to show adulteration.[40] To strengthen communication of information related to food safety and security threats to consumers, health care providers, and other stakeholders, the FDA will invest in improved, reliable, and integrated information technology systems to ensure that information gathered is reliable and accurate.[41]

Food safety laws and regulations will continue to evolve from their initial framework stages for the foreseeable future, and will likely be the subject of many *Food Law Updates* to come. Whether small to medium-sized food production and processing enterprises can withstand financially the increasing number of food safety mandates likely will be at the center of standards debates. It appears that the FDA has made some headway in ensuring that foreign producers and processors adhere to United States food standards, but only after food crises shook Americans' confidence in the safety of the food supply. The upcoming transition to a new administration, however, may delay, at least to some extent, the development of new food safety initiatives.

III. GRASS FED LIVESTOCK CLAIMS

The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), under the authority of the Federal Meat Inspection Act[42] and the Poultry Products Inspection Act,[43] oversees the labeling, standards, and ingredients for meat and poultry products sold in the United States. Accordingly, producers

39. *Id.* at 21.

40. FOOD PROTECTION PLAN, *supra* note 17, at 22. Various advocates have proposed mandatory recall authority for several years. *See* Michael T. Roberts, *Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety*, 59 FOOD & DRUG L.J. 563 (2004); Safe Food Act of 2007, S. 654, 110th Congress § 403 (notification and recall); FDA Food Safety Modernization Act, S. 3385, 110th Congress § 103 (2008) (mandatory recall authority).

41. *Id.* at 24.

42. 21 U.S.C. § 607 (2000).

43. *Id.* § 457.

must submit product labels with marketing claims to FSIS's Labeling Program and Delivery Division (LPDD) prior to use.

In an effort to distinguish their products from those of competitors, some segments of the livestock and meat industries include labeling claims referring to special attributes of their product or process.[44] To bolster claim credibility, the USDA's Agricultural Marketing Service (AMS), upon request, will act as a third-party verifier. Since 1978, the USDA has provided certification for various claims related to product traits and, starting in 1996, verification status for pre- and post-harvest process claims not subject to confirmation by product examination.[45] The verification programs collectively are known as the Quality System Verification Programs (QSVP).[46] As the number of organizations requesting USDA verification expanded, the agency determined that standardization of the various marketing and production label claims would permit consumers to make better informed purchasing decisions.[47]

Accordingly, in 2002, the AMS proposed standards for several livestock and meat marketing claims.[48] One proposed standard that engendered significant public comment was for animals raised on grass, green or range pasture, or forage throughout their life cycle, with only limited supplemental grain feeding–so-called "grass fed" claims.[49] The 2002 proposal required grass (or grass equivalents such as green or range pasture, or forage) to comprise at least 80%

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44. United States Standards for Livestock and Meat Marketing Claims, 67 Fed. Reg. 79552, 79553 (Dec. 30, 2002).

45. *Id.* at 79553.

46. *See* AGRIC. MKTG. SERV. (AMS), USDA, QUALITY SYSTEMS VERIFICATION PROGRAMS GENERAL POLICIES AND PROCEDURES, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103479.

47. 67 Fed. Reg. at 79553. For example, the number of producers claiming "grass-fed" status increased from fifty in 2000 to more than 1,000 in 2007. Jane Black, *Grass-Fed? Not Without Grass*, WASH. POST, Oct. 17, 2007, at F1.

48. 67 Fed. Reg. at 79554-56. Categories of proposed claims and standards relating to live animal production included: antibiotic claims, breed claims, free range claims, geographic location claims, grain fed claims, grass fed claims, hormone claims, livestock identification claims, preconditioning claims, and vitamin E claims. *Id.* at 79554-55. Claims related to meat product characteristics included: aged meat claims, electrical stimulation claims, and tenderness claims. *Id.* at 79555-56.

49. *Id.* at 79555. "Grass feeding usually results in products containing lower levels of external and internal fat (including marbling) than grain-fed livestock products." *Id.* In addition, consumers also perceive the product to be more environmentally friendly, healthier (due to higher levels of Omega-3 fatty acids), and better tasting than their grain-raised counterparts. Marian Burros, *New Rules Set for Meat Sold as Grass Fed*, N.Y. TIMES, Oct. 19, 2007, at A22; Black, *supra* note 47.

of the animal's primary energy source throughout its life cycle.[50] To ensure the animal's well-being at all times, the proposal allowed limited supplementation of grains or other non-grass-based feed during adverse environmental conditions.[51]

In 2006, the USDA, as a result of comments to the 2002 proposal, significantly revised its proposed "grass fed" labeling claim and requested additional public feedback.[52] The revised proposal addressed a variety of points of contention in the 2002 version, including grass dietary requirements, the use of stored forages, supplements, hormones, and animal confinement, as well as general concerns regarding verification, compliance, and labeling.[53]

The 2006 proposed rule increased the required grass and forage feed percentage from 80% to 99% of the total energy source for the lifetime of the animal.[54] The agency adopted the 99% standard to allow for the inadvertent exposure to nonforage feedstuffs and

50. 67 Fed. Reg. at 79555.

51. *Id.*

52. United States Standard for Livestock and Meat Marketing Claim, Grass (Forage) Fed Claim, 71 Fed. Reg. 27662, 27663 (May 12, 2006).

53. *See id.* at 27663-65. The agency more thoroughly addressed many of the verification, compliance, and labeling issues in its 2007 notice. *See* Grass (Forage) Fed Claim for Ruminant Livestock and the Meat Products Derived From Such Livestock, 72 Fed. Reg. 58631, 58635 (Oct. 16, 2007). Among the issues raised by commenters were the high costs of complying with the regulations governing the marketing claims, the lack of penalties for producers who violate the standards, and allegations that the standards have a discriminatory effect upon imported meat. *Id.* Some producers commented that the high price of complying with the requirements to receive grass fed certification was unduly burdensome upon small and mid-sized producers, even with the price premium such a claim carries. *Id.* Rather than suggesting that the AMS do away with its new requirements, some called for a transition period to give producers time to adjust to the new standards while continuing to market products using the grass fed distinction in the interim. *Id.* An Argentinean importer complained that the new standards would hinder international producers' ability to use a grass fed claim regardless of the fact that their animals are between 99% and 100% grass fed. *Id.* In response to these criticisms, the AMS pointed out that, while the cost of compliance is unfortunate, these are voluntary marketing regulations and are by no means required of meat producers. *Id.* at 58636. Additionally, it pointed out that the Agricultural Marketing Act of 1946 does authorize both fines and imprisonment for fraudulent marketing under the standards, although no specifics were spelled out by the AMS. *Id.* Rather than responding particularly to the claim that the standards discriminated against meat importers, the AMS simply articulated a willingness to develop similar label claims between the USDA and foreign agencies responsible for such claims in their individual countries. *Id.* at 58363.

54. 71 Fed. Reg. at 27664.

supplementation of diets for animal welfare purposes during periods of adverse environmental or physical conditions.[55]

The agency also considered, but rejected, a proposal to limit grass and forage consumption to only non-harvested grasses and to restrict the use of stockpiled or stored forage.[56] Supporters of this requirement argued that consumers would expect "grass fed" livestock to be "free range" and not fed in confinement.[57] The USDA acknowledged the "synergistic nature to grass feeding and free range conditions,"[58] but due to the diverse grass-feeding regimes across the nation,[59] the agency found this limitation impractical and unduly restrictive.[60] Rather, to satisfy consumer demand for both grass fed and free range products (and other attributes such as an absence of added hormones), the agency encouraged producers to distinguish their goods via separate, voluntary labeling claims.[61]

On October 16, 2007, the USDA responded to the comments it received regarding the 2006 proposal and provided notice of the final standards for the QSVP grass fed livestock marketing claims.[62] Although there was relatively little controversy in the proposed 99% grass or forage-based diet requirement, some commenters remarked that the reference to the percentage energy source was unclear.[63] For example, one suggestion advocated changing the 99% "energy source requirement" to 99% of "dry matter intake" because the per-

55. *Id.* Exceptions include milk consumed prior to weaning as well as routine mineral and vitamin supplementation. *Id.* at 27665.

56. *Id.* at 27664.

57. *Id.*

58. "Granted, most grass (forage) fed livestock will also qualify as free range livestock (not fed in confinement); however, not all free range livestock will receive their entire energy source from grass or forage." *Id.*

59. For example, in southern states with adequate rainfall and a temperate climate, year round range feeding may be a practical alternative. In contrast, in western states with substantial dry periods and in northern states with significant snow or ice, continuous range feeding is not sustainable. 71 Fed. Reg. at 27664.

60. *Id.*

61. *Id.* The USDA proposed standards for "naturally raised" products on November 28, 2007. Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from Such Livestock, 72 Fed. Reg. 67226 (Nov. 28, 2007). The proposed "naturally raised" label claim prohibits the use of antibiotics and growth hormones, but still does not address the issue of animal confinement in feedlots. *Id.* at 67227. The comment period closed on March 3, 2008. Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from Such Livestock, 73 Fed. Reg. 5781 (Jan. 31, 2008) (extending the period for public comments).

62. Grass (Forage) Fed Claim for Ruminant Livestock and the Meat Products Derived From Such Livestock, 72 Fed. Reg. 58631 (Oct. 16, 2007).

63. *Id.* at 58633.

centage of intake is more commonly and easily calculated than the percentage of an animal's energy source.[64] Another suggested that, as a practical matter, a standard requiring a 100% grass or forage-based diet would be considerably easier to calculate and verify than the proposed 99% minimum.[65] One commenter argued that the USDA should support its percentage requirement with scientific data; however, the agency declined the invitation, noting that grass fed certification is a marketing claim, not a scientific computation.[66]

The agency, after a consideration of the issues raised by the comments, adopted a 100% grass or forage-based diet standard for the "grass fed" claim.[67] The change from 99% to 100% primarily resulted from criticism that calculating and verifying the 99% standard was unnecessarily difficult, especially considering that there is little practical difference between the two amounts.[68] The agency further decided to remove the "energy source" language in the standard in order to clarify that supplemental sources of energy and protein are not permitted under the grass fed claim.[69] To the extent incidental or emergency non-forage supplementation occurs, producers must fully document the amount, frequency, and substance of the exposure.[70]

Unlike the issue of diet percentage, commenters were divided starkly regarding the use of stored and harvested forages in the grass fed claim.[71] Some argued that no stored or harvested forages should be permitted, while others noted that the varying climates of the country required the allowance of stored quantities to supplement grazing.[72] Those who believed that stored and harvested forages should not fall within the grass fed claim standards asserted that allowing materials such as fermented vegetative products should not be permissible because they may have "undergone significant chemical alteration."[73] Others suggested that the grass fed designation should be available only to animals raised on 100% live,

64. *Id.*
65. *Id.*
66. *Id.*
67. 72 Fed. Reg. at 58633.
68. *Id.*
69. *Id.*
70. *Id.*
71. *Id.* at 58634.
72. 72 Fed. Reg. at 58634.
73. *Id.* (noting specifically that silage should not be permitted within the grass fed designation).

green grass, prohibiting the use of materials like hay and almond hulls.[74]

Opponents of such strict requirements commented that harvested grass and forage are necessary to sustain healthy animals during harsh winter conditions and droughts.[75] These commenters pointed out that, in many northern climates, animals cannot graze year-round, making it impossible to sustain livestock that would meet a standard requiring 100% live, green grass.[76] Regarding additional dietary supplements, many argued against the allowed use of a myriad of supplements, generally arguing that inclusion compromises purity.[77] Others opined that vitamin and mineral supplements often are required to maintain the health of animals, especially in areas with water quality concerns.[78]

The USDA ultimately reaffirmed its 2006 decision in which it found that limiting the grass fed designation to animals exclusively fed live grass was impractical because of the wide range of climates exiting across the United States.[79] By allowing certain stockpiles of stored and harvested forages within the grass fed standard, the agency ensured that the welfare of animals can be adequately addressed without compromising the integrity of the designation.[80] Although the USDA's final standard will allow vitamin supplements and selected minerals in order to adjust for possible diet deficiencies,[81] it prohibited some supplements, including cereal grains, grain byproducts, cottonseed meal, and soybeans.[82]

Closely related to the stored forage issue is the amount of time that grass fed livestock must spend with access to pasture.[83] The 2006 proposal did not address directly this limitation. Many of those who submitted comments to the AMS argued that the term "grass fed" should only be applied to animals raised exclusively on

74. *Id.*
75. *Id.*
76. *Id.*
77. *See* 72 Fed. Reg. at 58634.
78. *Id.*
79. *Id.*
80. *Id.*
81. *Id.* at 58634-35.
82. 72 Fed. Reg. at 58634-35.
83. *Id.* at 58635.

pasture, while others believed the standard should require only a percentage of the animal's time to be spent at pasture.[84] One commenter suggested that grass fed animals should be required to graze pasture during the entire growing season, with the possible exception of times during emergencies and management practices required for routine maintenance.[85] The agency observed that consumers reasonably expect grass fed animals to have been raised on pasture rather than in other forms of confinement.[86] Moreover, it agreed with commenters that grazing on live pasture during the growing season is inherent in the term "grass fed." Due, again, to climate variations, the agency resisted calls to require year-round free-range grazing on live pasture, noting that a separate free-range distinction could be made for marketing purposes.[87] Accordingly, the final standard requires "continuous access to pasture during the growing season."[88]

Finally, some commenters argued that the treatment of grass fed animals with antibiotics and hormones should be prohibited.[89] Without discussing the specific arguments championed by supporters and opponents of such a requirement, the agency acknowledged the complexity of the issue and, rather than crafting a compromised position, abstained from incorporating hormone and antibiotic bans in the grass fed standards. It noted that such a distinction would be more appropriate as a separate marketing claim—a similar result to the free-range access to pasture debate discussed above.[90]

Although the USDA's final decision adopted a seemingly stringent 100% dietary standard, the rule fell far short in many respects, according to the American Grassfed Association (AGA).[91] The AGA, a trade association representing many raisers of grass fed livestock,[92] pushed for year-round pasture access along with a prohibition of the use of growth hormones and antibiotics.[93] Failure to require these

84. *Id.*
85. *Id.*
86. *Id.*; Burros, *supra* note 49.
87. 72 Fed. Reg. at 58635.
88. *Id.* at 58637.
89. *Id.* at 58635.
90. *Id.*
91. Press Release, Am. Grassfed Ass'n (AGA), American Grassfed Association Position Statement on the Newly Released USDA Grass Fed Claim (Oct. 16, 2007), *available at* http://www.americangrassfed.org/pdf/Press%20release%2010-16-07%20USDA%20claim.pdf
92. AGA, http://www.americangrassfed.org (last visited July 15, 2008).
93. Burros, *supra* note 49.

measures, according to the AGA, is certain to create confusion in the marketplace as consumers' expectations of grass fed products will not be met by the USDA process verified label. Moreover, other producers can use a grass fed-type claim without even following the USDA standards because the verification process is voluntary. Accordingly, the AGA announced its own industry-backed standard for certifying grass fed meat operations.[94] The AGA program is intended to exceed the requirements of the USDA program by prohibiting confinement, antibiotics, and added hormones.[95]

The AGA's industry-based efforts to create a more stringent product label to satisfy consumer expectations are not unique to the grass fed beef market. Tension between the minimum standards of government-backed food labels and industry demands to further differentiate their products via specialized labeling to meet multifaceted consumer expectations is a trend unlikely to waiver so long as consumers remain willing to pay for process-based attributes. For example, the organic industry has long struggled with competing views of what production processes should qualify for the USDA's organic seal.[96] Two examples from the second half of 2007 further illustrate this point: litigation involving the Cornucopia Institute and several large-scale organic dairies and a revision and update of the National Organic Program's National List of Allowed and Prohibited Substances. The following section briefly discusses each of these developments.

94. *Grass-fed beef producers approve new labeling standard*, SUSTAINABLE FOOD NEWS, Feb. 20, 2008, *available at* http://www.americangrassfed.org/pdf/articles/Grassfed_beef_approve_new_label.pdf.

95. *Id.*

96. A. Bryan Endres, *An Awkward Adolescence in the Organics Industry: Coming to Terms with Big Organics and Other Legal Challenges for the Industry's Next Ten Years*, 12 DRAKE J. AGRIC. L. 17, 19-23 (2007) (analyzing the divide between "Big Organic" and "Organic as Religion" in the development of organic standards from the late 1970s through the 2005 amendments to the Organic Foods Production Act (OFPA)).

IV. DEVELOPMENTS IN ORGANIC PRODUCTION STANDARDS

A. Organic Dairy Operations

When passed by Congress in 1990, the Organic Foods Production Act (OFPA),[97] for the most part, adopted consensus standards based in part on the various organic production regimes at the state level.[98] The OFPA consolidated these standards into the National Organic Program (NOP) and charged the United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) with developing implementing regulations.[99] Unlike their organic grain and produce counterparts, organic livestock programs were undeveloped in 1990. Prior to the OFPA's passage, the USDA, under the authority of the Meat Inspection Act and the Poultry Products Inspection Act, explicitly prohibited the use of the term "organic" with meat and poultry products. As a result, few livestock producers had entered the organic market and little consensus (or production expertise) existed at the time of the congressional debates as to what should constitute "organic" meat, poultry, or milk products.

Given the lack of general agreement, Congress charged the National Organic Standards Board (NOSB) with determining the details of organic livestock production.[100] Congress's failure to specify organic production standards for livestock in the OPFA resulted in more than a decade of conflict within the USDA as the agency attempted to craft acceptable animal welfare standards for the organic program.[101]

Most of the controversy to date centers on the amount of pasture (as opposed to feedlot confinement) required for organically raised livestock. In 2005, the NOSB recommended an amendment to the NOP rules that would require ruminants to graze on pasture

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97. Food, Agriculture, Conservation and Trade Act of 1990, Pub. L. No. 101-624, § 2101, 104 Stat. 3359, 3935 (codified as amended at 7 U.S.C. §§ 6501-6522 (2006)).

98. S. Rep. No. 101-357, at 289 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 4546, 4943.

99. *Id.*

100. Chad M. Kruse, *The Not-So-Organic Dairy Regulations of the Organic Food Production Act of 1990*, 30 S. ILL. U.L.J. 501, 504-06 (2006) (discussing the legislative history of the livestock provisions of the OFPA).

101. *See* Endres, *supra* note 96, at 45-48 (discussing the debate over the access to pasture rules in the organic standards).

during the growing season.[102] Rather than finalize proposed rules for public comment, the USDA instead decided to engage in additional fact finding on the already exhaustively vetted NOSB proposal.[103]

While the USDA debated the respective merits of proposed pasture requirements, demand for organic dairy products skyrocketed.[104] To meet consumer demand (and to gain the attendant profits available in the organic market), some large-scale dairy operations sought and received organic certification. Scale efficiencies led these producers to feedlot production systems rather than the pasture-based systems envisioned by many in the organic community.[105] The Cornucopia Institute, an organic advocacy organization, filed a series of complaints with the USDA, alleging that some of these large-scale producers were violating not only the "spirit" of the organic standards, but the minimum legal requirements as well.[106]

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102. Nat'l Organic Standards Bd. (NOSB), *Formal Recommendation to the National Organic Program*, March 18, 2005, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3104502.

103. National Organic Program (NOP)–Access to Pasture (Livestock), 71 Fed. Reg. 19131 (April 13, 2006). As this article went to press, the USDA issued proposed rules for pasture access. *See* National Organic Program (NOP)-Access to Pasture (Livestock), 73 Fed. Reg. 63584 (Oct. 24, 2008).

104. *See* CAROLYN DIMITRI & KATHRYN M. VENEZIA, ERS, RETAIL AND CONSUMER ASPECTS OF THE ORGANIC MILK MARKET (2007), *available at* http://www.ers.usda.gov/publications/LDP/2007/05May/LDPM15501/ldpm15501.pdf (noting that demand for organic milk increased 25% in 2005); Kim Severson, *An Organic Cash Cow*, N.Y. TIMES, Nov. 9, 2005, at F1 (noting that although organic milk comprises only 3% of total milk sales, the annual growth rate for or organic milk was 23%, while overall milk consumption fell by 8%).

105. Many comments to the NOP Final Rule (as well as the NOSB itself) recommended that all ruminant production systems, specifically beef and dairy cattle, be pasture-based and that the rules should prohibit feedlot confinement except under certain circumstances. National Organic Program (NOP)–Access to Pasture (Livestock), 71 Fed. Reg. 19131 (Apr. 13, 2006).

106. *See* Cornucopia Inst., Complaint concerning multiple violations of the National Organic Program's regulatory standards by the Aurora Organic Dairy Farm (AOD), *available at* http://www.cornucopia.org/AuroraTexasFarm/3rdAurora LegalComplaint_7-06_Final.pdf (on file with author); Cornucopia Inst., Complaint concerning multiple violations of the National Organic Program's regulatory standards by the Horizon Organic Dairies, *available at* http://www.cornucopia.org/HorizonComplaint8-06.pdf (on file with author). *See also* MARK KASTEL, CORNUCOPIA INST., MAINTAINING THE INTEGRITY OF ORGANIC MILK, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3479182. Cornucopia later filed suit against the USDA under the Freedom of Information Act for documents regarding the operations of several large scale organic dairies. *See* Cornucopia Inst., *Organic Watchdog Sues USDA*, http://www.cornucopia.org/index.php/organic-watchdog-sues-usda (last visited July 15, 2008;

On April 16, 2007, the UDSA issued a Notice of Proposed Revocation to Aurora Organic Dairy (AOD) of Boulder, Colorado, the owner of eight organic dairy operations.[107] The USDA's Notice identified fourteen violations of the NOP.[108] Alleged violations generally focused on three areas: failure to establish and maintain access to pasture, transfer of dairy cattle between organic and non-organic production methods, and failure to maintain and disclose adequate records of the production operations.[109]

AOD entered into a Consent Agreement with the UDSA on August 23, 2007.[110] Under the agreement, AOD agreed to decertify one of its eight dairy operations.[111] A second operation must file an amended organic system plan.[112] Finally, AOD's Platteville facility must remove animals not under continuous organic management, limit grazing densities, provide access to pasture during the growing season for both lactating and dry dairy animals, and reduce the total number of animals at the facility in order to comply with the pasture density requirements.[113]

Despite what Cornucopia and the USDA alleged were willful violations of the OFPA, the USDA allowed AOD to remain in the organic business and did not levy any fines against the organization. Organic regulations authorize a civil penalty of not more than

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on file with author). The court later dismissed the case as moot after the agency released 2,500 pages of documents. *See* Cornucopia Inst., *Organic Watchdog Obtains Suppressed Public Documents from USDA Lawsuit*, http://www.cornucopia.org/index.php/organic-watchdog-obtains-suppressed-public-documents-from-usda-lawsuit (last visited July 15, 2008; on file with the author).

107. USDA, Notice of Proposed Revocation (AOD), April 16, 2007, *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5063457&acct=nopgeninfo (on file with author). In addition to the agency's action against AOD, a second operation that was the target of complaints, Vander Eyk Dairy in California, received notice from its organic certifier, Quality Assurance International, of deficiencies to be corrected to avoid suspension of its certification. *See* Letter from Quality Assurance Int'l to Case Vander Eyk, Jr., Feb. 22, 2007, *available at* http://www.cornucopia.org/VanderEyk/LetterFromCertifier.pdf (on file with author).

108. USDA, Notice of Proposed Revocation (AOD), *supra* note 107.

109. *Id.*

110. AMS, Consent Agreement–Aurora Organic Dairy, M-005-06 (Aug. 23, 2007), *available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5063456&acct=nopgeninfo.

111. *See id.* § 7(h) (agreeing to remove AOD's Woodward facility located in Greeley, Colorado from organic certification).

112. *See id.* § 10 (agreeing to submit an amended organic system plan for the Dublin, Texas facility).

113. *See id.* § 7 (outlining compliance measures for the Platteville facility).

$11,000 per violation for any operation that knowingly sells or labels a product as organic that does not meet the OFPA's standards.[114] The agency's decision not to penalize AOD was especially disappointing to Cornucopia because, during the time that AOD violated the standards, the dairy built a substantial market share and drove down the price for other organic farmers.[115] As a post-script to this controversy, consumers in twenty-seven states have filed class action lawsuits against AOD alleging consumer fraud, negligence, and unjust enrichment from the sale of milk labeled as "organic."[116]

B. Updating the National List

Limited sourcing of key organic ingredients remains a barrier to obtaining market share, or at the very least, meeting the expanding consumer demand for organic certified processed foods.[117] Accordingly, the inclusion (or, conversely, the exclusion) of particular ingredients and production inputs on the NOP's National List[118] continued to engender significant controversy in the second half of 2007.

One aspect of the National List, especially relevant to multi-ingredient processed foods, is commercial availability. Items not

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114. 7 C.F.R. § 3.91(b)(1)(xxxvii) (2007).

115. Cornucopia Inst., *USDA Enforcement Action at Nation's Largest Dairy Fails to Levy Fines or Yank Certification*, http://www.cornucopia.org/index.php/usda-finds-largest-organic-dairy-perpetrating-fraud-fails-to-levy-fines-or-yank-certification (last visited July 15, 2008).

116. Complaint, Mothershead v. Aurora Dairy Corp., No. 07CV01701, 2007 WL 3033573 (E.D. Mo. Oct. 4, 2007) (first of several class actions filed against AOD); *In re* Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig., No. 4:08MD01907 ERW, 2008 WL1805731 (E.D. Mo. Apr. 18, 2008) (ordering the filing of a consolidated class action complaint). *See also* Cornucopia Inst., *Lawsuits Announced Against Nation's Biggest Organic Dairy*, http://www.cornucopia.org/index.php/lawsuits-announced-against-nations-biggest-organic-dairy-2 (last visited July 15, 2008).

117. *See* George C. Kalogridis, *Contracting Your Way to Sourcing Success*, ORGANIC PROCESSING, Mar.-Apr. 2008, at 22, 26 (describing how sourcing of organic ingredients is different from that of conventional ingredients and the need for constant strategy adjustment to secure the necessary supply).

118. The National List is the USDA's official listing of approved and prohibited substances used in organic production and handling. 7 U.S.C. § 6517(a) (2006). The list outlines synthetic substances that may be used, as well as nonsynthetic substances that may not be used in organic production and handling. 7 C.F.R. §§ 205.600-.607 (2008). As a general rule, synthetic substances may not be used for organic production or handling unless specified on the National List. *Id.* § 205.105(a).

commercially available in organic form[119] may be used in organic foods bearing the USDA "organic" seal, which must be at least 95% organic.[120] Prior to 2007, individual certifiers, on an ad hoc basis, determined commercial availability for specific ingredients. In *Harvey v. Veneman*,[121] the court held that the agency, rather than individual certifying operations, must make the unavailability determination and must publish those unavailable products on the National List.[122] On remand, the district court allowed the USDA until June 2007 to update the National List to reflect commercially unavailable items.[123]

The USDA received almost 100 petitions to add more than 600 agricultural ingredients to the list as not available commercially in organic form.[124] The agency, after an initial review, forwarded seventy-nine petitions to add fifty-two substances to the NOSB for further evaluation under the NOP's criteria.[125] In March 2007, the NOSB voted to add thirty-eight ingredients.[126] On May 15, 2007, the USDA published a proposed rule that amended the National List to

119. *See* 7 C.F.R. § 205.606 (2008) (listing nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic").

120. *See id.* § 205.301(b). The remaining 5% must be organically produced unless they are "not commercially available in organic form" or are "nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List." *Id.*

121. *See* Harvey v. Veneman, No. Civ. 02-216-P-H, 2003 WL 22327171 (D. Me. Oct. 10, 2003) (Magistrate Judge's report and recommendation on cross motions for summary judgment), *aff'd in part, rev'd in part*, 297 F. Supp. 2d 334 (D. Me. 2004), *aff'd in part, rev'd in part and remanded*, 396 F.3d 28 (1st Cir. 2005), *superseded by statute*, Agriculture, Rural Development, Food and Drug Administration and Related Appropriations Act of 2006, Pub. L. No. 109-97, 119 Stat. 2120, *as recognized in* Harvey v. Johanns, 462 F. Supp. 2d 69 (D. Me. 2006).

122. *Id.* at 36. *See* 7 C.F.R. § 205.606 (2008) (listing items allowed when not commercially available in organic form).

123. Amendments to the National List of Allowed and Prohibited Substances (Processing)—Interim Rule with Request for Comments, 72 Fed. Reg. 35137, 35137 (June 27, 2007).

124. *Id.* at 35138.

125. *Id.*

126. *Id.* The NOSB website posts the board's recommendations for each of the thirty-eight items. NOSB Final Recommendations, March 2007, http://www.ams.usda.gov (follow "National Organic Program" hyperlink, then "National Organic Standards Board" hyperlink, then "Read Recommendations" hyperlink; last visited July 15, 2008).

include those thirty-eight NOSB recommended ingredients[127] and issued an Interim Final Rule on June 27, 2007.[128]

While considering the commercial availability petitions resulting from the *Harvey* litigation, the NOSB also re-evaluated 168 substances already included on the National List[129] as a part of the mandatory sunset review of all National List items.[130] The OFPA requires re-evaluation of each item on the National List every five years.[131] Items included on the USDA's original National List in October 2002 automatically expired in October 2007.[132] Accordingly, the NOSB reviewed the 168 items subject to expiration—recommending 165 for renewal and removing three.[133]

A lenient construction by the NOSB or the USDA's AMS of what constitutes unavailability in the commercial context allows the organic processed foods market to expand without fear of essential ingredient shortages due to lack of an organic supply. On the other hand, failure to rigidly apply unavailability standards sends a market signal to potential suppliers of the organic counterpart to forgo investment in new product development (i.e., conversion from conventional to organic production) and may lead to accusations that the agency is lowering organic standards for the benefit of large-scale, processed organic food companies. Similar arguments apply to the NOSB's National List sunset review of synthetic production or processing aids. An overly restrictive interpretation could upset settled organic industry practices and restrict sourcing options. Blanket renewal of National List items, however, would eviscerate the intent behind the sunset review process—encouraging the development of organic forms of substances and avoiding, whenever possible, the use of synthetics.

Behind the scenes struggles between large-scale organic operations and self-proclaimed watchdogs such as the Cornucopia Institute and Arthur Harvey, the plaintiff in the first legal challenge to

127. Proposed Amendments to the National List of Allowed and Prohibited Substances (Processing), 72 Fed. Reg. 27252 (May 15, 2007) (codified at 7 C.F.R. pt. 205).

128. 72 Fed. Reg. at 35138 (listing items added as not commercially available).

129. *See* National Organic Program, Sunset Review, 72 Fed. Reg. 58469, 58469 (Oct. 16, 2007) (codified at 7 C.F.R. pt. 205).

130. *See id.*

131. 7 U.S.C. § 6517(e) (2006).

132. *See* National Organic Program, Sunset Review, 70 Fed. Reg. 35177, 35177 (June 17, 2005) (soliciting comments for NOSB consideration).

133. *See* 72 Fed. Reg. at 58469.

the organic programs implementing regulations,[134] will be a continued feature of the organic industry for the foreseeable future. So long as consumers remain confident in the product (and willing to pay more for the special attributes conveyed by the organic label) the legal debates between organic idealism and the profit potential inherent in this expanding consumer market are a healthy element in the organic debate. Should this become too contentious and the public lose confidence, the parties risk sacrificing the organic goose that is laying the golden egg.

V. IRRADIATION FOOD LABELING

As noted in the introduction, the Food and Drug Administration's (FDA) proposed revision of irradiated food labeling generated substantial public interest during the second half of 2007 and warrants at least an introductory discussion at this time to frame the debate. On April 4, 2007, the FDA submitted a proposal for public comment suggesting a change in the regulation of labels for irradiated food products.[135] Although manufacturers irradiate only a small portion of items on the market, the FDA has approved irradiation as a generally safe practice for many food products.[136] Currently, food treated by irradiation must indicate such treatment by including the radura logo and a disclosure statement on its label.[137] The FDA's proposed rule differs from the current rule in two major respects. First, it would require labeling food as irradiated only if the treatment causes a material change in the food. Second, labels of those items requiring irradiation labeling must include specific language describing the material change caused by the irradiation.[138] In addition, the proposed rule authorizes, in certain limited circumstances, substitution of the term "irradiated" with "pasteurized."[139]

The FDA has statutory authority to mandate certain food labels when the absence of a labeling statement fails to disclose material facts to the consumer.[140] Under its new irradiated food proposal, the

134. *See* Harvey v. Veneman, *supra* note 121.

135. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291, 16291 (Apr. 4, 2007).

136. *Id.* at 16294.

137. *Id.* at 16292 (noting that the "disclosure statement" can be as simple as "treated with radiation").

138. *Id.* at 16300.

139. *Id.*

140. 21 U.S.C. § 343(a) (2000) (defining a food as misbranded if the label is "false or misleading in any particular"); § 321(n) (noting that misbranding includes con-

FDA would require irradiation disclosure only when the treatment resulted in a material change in the food[141]—a nutritional, organoleptic,[142] or functional alteration.[143] The FDA would determine materiality on a case-by-case basis, as the same change could be of importance to the use or consumption of some foods but not others.[144] For example, extending the shelf life of spices through irradiation may be immaterial; however, extending banana shelf life might be a material change because of its varying uses.[145] What qualifies as a material change is likely to be a point of considerable controversy, because the FDA considers the primary result of irradiation, the control of foodborne pathogens, to be immaterial—a determination that will eliminate a label designation for most irradiated food.[146]

In many respects, the irradiation labeling proposal closely tracks the agency's current "process versus product" labeling guidance distinction for foods derived from genetically engineered crops,[147] and is consistent with the agency's long-stated position that the regulatory status of food is dependent upon the objective characteristics and intended use of the food, irrespective of the process by which the product is developed.[148] A method of production that does not result in an altered product characteristic is not material

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sideration of the extent to which the label fails to reveal material facts or consequences resulting from the use of the article).

141. 72 Fed. Reg. at 16300.

142. *Id.* at 16293 (defining the term "organoleptic" to mean a change in taste, smell or texture).

143. *Id.*

144. *Id.* at 16294 (noting that material changes cannot be determined using a blanket approach).

145. *Id.* (noting that bananas may be purchased for a use dependent upon quick ripening and thus, the purpose of the product may be frustrated by extending its shelf life).

146. 72 Fed. Reg. at 16295 (noting that controlling foodborne pathogens does not materially change food because consumers expect food to be safe and irradiation simply helps to ensure safety rather than causing an unexpected change).

147. *See* Statement of Policy: Food Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992) (establishing FDA policy requiring labeling of foods derived from genetically engineered plants only under certain circumstances); Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001) (reaffirming the agency's 1992 policy regarding mandatory labeling and providing additional guidance for voluntary label statements). For a recent discussion of biotech food labeling rules and impacts, see LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE (Paul Weirich ed., 2007).

148. 57 Fed. Reg. at 22984.

information and does not require disclosure on the food label.[149] Under this line of reasoning, the FDA generally does not require labels to indicate a food derived from genetic engineering.[150]

From the consumer perspective, the difference between labeling for the presence of genetic engineering and irradiation may rest on consumer expectations. Consumers have grown accustomed to the process-based labeling regime for irradiated products and are able to make choices to reflect their consumption preference. Substituting a product-based regime will increase transaction costs for those consumers who seek to avoid irradiated products, similar to consumers' attempts to avoid genetically engineered products by seeking out certified organic or natural products.[151]

On the other hand, the FDA's market research suggests that consumers generally do not understand what is meant by the term "irradiated," a fact which could lead to an unjustified fear that the term is a government-mandated warning rather than simply informational.[152] Research suggests that a brief description of the purpose of the irradiation is helpful in assisting in consumer education.[153] Some comments suggested that explanatory phrases such as "irradiated to kill harmful bacteria" would be helpful,[154] but criticized phrases such as "electronic pasteurization" as misleading.[155] The 1986 final rule (the current rule) allows, but does not require, the manufacturer to include a statement on the label that explains the

149. *Id.* at 22991 (citing 21 U.S.C. § 321(n) which requires disclosure of material information on food labels).

150. Products derived from genetic engineering that have a significant change in the composition of the food would require a label. *See* FDA, *Q&A Sheet: FDA's Statement of Policy; Foods Derived from New Plant Varieties* (1992), *available at* http://www.cfsan.fda.gov/~lrd/bioqa.html; 66 Fed. Reg. at 4839 (outlining four situations mandating labeling: (1) "[i]f a bioengineered food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food," (2) "[i]f an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use," (3) "[i]f a bioengineered food has a significantly different nutritional property," or (4) "[i]If a new food includes an allergen that consumers would not expect to be present based on the name of the food").

151. *See* Endres, *supra* note 96, at 41-42 (noting that demand for organic products is motivated, at least in part, by consumers seeking to avoid genetic engineering).

152. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291, 16292-93 (Apr. 4, 2007) (to be codified at 21 C.F.R. pt. 179).

153. *Id.* at 16292-93.

154. *Id.* at 16292.

155. *Id.* at 16292-93.

purpose of the treatment.[156] In accordance with the materiality standard discussed above, the proposed rule will require explicit language describing the material change in the food or its condition of use (e.g., "irradiated to inhibit sprouting").[157]

In a further departure from the agency's previous bright-line rule regarding labeling of irradiated food, the FDA's proposed rule would allow the substitution of the term "pasteurized" for "irradiated."[158] Those seeking to use the term "pasteurized" would have to notify the FDA and provide data demonstrating that the process was "reasonably certain to achieve destruction or elimination in the food of the most resistant micro-organisms of public health significance."[159] Upon receiving notice of the proposed label use, the agency would have 120 days to object.[160]

In sum, the FDA argues that the revised irradiation rules will provide consumers with more information because those products requiring labeling will also have additional information explaining the material change. In addition, elimination of some irradiation labels could have a positive impact on public health by altering purchasing patterns of consumers who previously avoided irradiated products due to unfounded safety concerns.[161] The agency noted that eliminating the label on products without irradiated-inducted material changes will allow more consumers to receive the potential health benefits that may be derived from consuming irradiated foods.[162] On the other hand, elimination of mandatory irradiation labeling on all products will make it much more difficult for consumers to exercise their right to purchase products not subjected to radiation.

It bears remembering that in February 1984, the FDA proposed significant revisions to its irradiation policy.[163] One item that engendered particular attention at the time was a proposal to eliminate

156. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13376, 13387-88 (Apr. 18, 1986) (codified at 21 C.F.R. pt. 179).

157. *Id.* at 16296.

158. *Id.* at 16293.

159. *Id.* (describing changes to 21 U.S.C. § 343(h)(3) required by the Farm Security and Rural Investment Act of 2002, Pub. L. 107-171, 116 Stat. 530, that mandate that the FDA develop new criteria for use of the term "pasteurized").

160. *Id.*

161. 72 Fed. Reg. at 16301.

162. *Id.*

163. Proposed Rule: Irradiation in the Production, Processing and Handling of Food, 49 Fed. Reg. 5714 (Feb. 14, 1984).

irradiated food labeling requirements at the retail level.[164] Of the 5,000 comments received by the agency regarding the proposed modifications, half addressed the retail labeling issue, of which over 80% urged the agency to require labeling to prevent consumer deception.[165]

In an era prior to genetic engineering's "process versus product" distinction in food labeling, the agency justified mandatory irradiation labeling because "[i]rradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed."[166] The agency further noted that whether such information is material under 21 U.S.C. section 321(n) "depends not on the abstract worth of the information but on whether consumers view such information as important and whether the omission of label information may mislead a consumer."[167] The agency considered the large number of consumer comments in opposition to the proposed elimination of irradiation labeling to be evidence of the significance placed on irradiation labeling.[168]

The FDA acknowledges that in recent years its labeling policies "have focused on the results of the processing of the food rather than the processing itself."[169] Its proposed rule follows this trend. Whether substantial consumer objection to the labeling change will be sufficient to alter agency policy remains to be seen. If not, observers of food law and policy may question whether the agency will revise other process-based labeling requirements that have a minor impact on the finished product.[170]

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164. *Id.* at 5718-19.

165. Irradiation in the Production, Processing and Handling of Food, 51 Fed. Reg. 13376, 13387 (April 18, 1986).

166. *Id.* at 13388.

167. *Id.*

168. *Id.* The agency dismissed concerns regarding the implied "warning" impact of irradiation labeling and noted that proper consumer education could correct any confusion. 51 Fed. Reg. at 13389 ("Although FDA recognizes the potential for consumer confusion, because there is no safety problem with food irradiated in accordance with this final rule, any confusion created by the presence of a retail label requirement can be corrected by proper consumer education programs . . .").

169. Irradiation in the Production, Processing and Handling of Food, 72 Fed. Reg. 16291, 16295 (Apr. 4, 2007) (to be codified at 21 C.F.R. 179).

170. In the FDA's 1986 publication of the Final Rule retaining food irradiation labeling, the agency discussed several process-based labels. *See* Irradiation in the Production, Processing, and Handling of Food–Final Rule, 51 Fed. Reg. 13376, 13388 (Apr. 18, 1986) (codified at 21 C.F.R. pt. 179). One process-labeling example from the 1986 document with a potential minor impact is the requirement to label products made from previously concentrated ingredients. *Id.*

VI. CONCLUSION

After devoting substantial resources reacting to a series of food safety crises during the second half of 2006 and early 2007, government attention shifted to food safety planning with an emphasis on prevention. The Food and Drug Administration (FDA) Food Protection Plan proposes substantial changes not only in agency emphasis, but also in legislative authority. These proposals warrant close attention in the future as the agency translates its plan into action. In addition to safe food, American consumers continue to demand an ever increasing array of food products with special attributes. Debates regarding grass fed beef labeling and standards for organic certification illustrate the difficulty of reconciling standards to simultaneously satisfy consumer expectations and industry production concerns. The final topic in this edition of the *Update*—food irradiation labeling—is yet another example of an agency attempting to mediate potential conflict between consumers' expectations and the food industry. The FDA's ultimate resolution of the irradiation labeling issue may provide insight into the agency's "process versus product" labeling philosophy and the deference afforded to consumers' desires for food product information to guide their purchasing decisions.